IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P.; NESTLÉ SKIN HEALTH S.A.; and TCD ROYALTY SUB, LLC,	:	
Plaintiffs,	:	
v.	:	C.A. No. 16-207-LPS
AMNEAL PHARMACEUTICALS LLC; and AMNEAL PHARMACEUTICALS CO. (I) PVT. LTD.,	:	
Defendants.	:	

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MEMORANDUM OPINION

May 9, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

On March 31, 2016, Plaintiffs Galderma Laboratories, L.P.; Nestlé Skin Health S.A.; and TCD Royalty Sub, LLC ("Galderma" or "Plaintiffs") filed suit against Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Co. (I) Pvt. Ltd. ("Amneal" or "Defendants"), alleging infringement of U.S. Patent Nos. 7,211,267 (the "'267 patent"); 7,232,572 (the "'572 patent"); 8,603,506 (the "'506 patent"); 9,241,946 (the "'946 patent"); 7,749,532 (the "'532 patent"); 8,206,740 (the "'740 patent"); 8,394,405 (the "'405 patent"); 8,394,406 (the "'406 patent"); 8,470,364 (the "'364 patent"); and 8,709,478 (the "'478 patent"). (D.I. 1 ¶ 6) The patents-in-suit are directed to doxycycline formulations that treat papules and pustules of acne and rosacea.

Presently before the Court is the issue of claim construction. The parties submitted claim construction briefs. (*See* D.I. 69, 70, 74, 75) The Court held a claim construction hearing on March 10, 2017. (*See* D.I. 85 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . .

[which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven

when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d

at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. "results in no reduction of skin microflora during a six-month treatment"[1]

Plaintiffs Plain and ordinary meaning, i.e., "wherein the amount results in no reduction of skin microflora vis-à-vis a placebo control during a six-month treatment, with microbiological sampling at baseline and month 6"
Defendants "an amount that [...] results in no reduction of any microorganisms, e.g., bacteria, anywhere on the skin, at any time over the course of a six-month treatment"[2]
Court "wherein the amount results in no reduction of skin microflora vis-à-vis a placebo control during a six-month treatment, with microbiological sampling at baseline and month 6"

The parties' dispute "centers on which qualifications should be applied to the claim language concerning the reduction of skin microflora." (D.I. 69 at 9) Defendants argue that "nothing in the claims limits what areas of the skin must see 'no reduction in skin microflora.'" (*Id.*) Defendants further argue that nothing in the claims "limit[s] what strains of skin microflora must be assessed for possible reduction, . . . how much of [a] reduction can occur, or how one should measure for reduction." (*Id.*) The Court disagrees with Defendants.

The specification supports Plaintiffs' construction. Example 38 in the specification "describes [a] placebo-controlled clinical trial that assesse[s] the amount of reduction of skin microflora from a six-month treatment" with "[m]icrobiological sampling at baseline and month 6." (D.I. 70 at 10; '506 patent col. 20 ll. 12) Example 38 further describes the result: "no

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[1]This term appears in claims 28-30 of the '267 patent; claims 1 and 20 of the '572 patent; claims 1, 8, and 15 of the '506 patent; and claims 1, 7, and 13 of the '946 patent. (*See* D.I. 77 at 2-3)

[2]Defendants do not seek to construe any of the bracketed text.

reduction of skin microflora . . . when compared with placebo." '506 patent col. 20 ll. 34-37. Example 38 is "the sole specific description in the ['267, '572, '506, and '946] patents of [the] testing and results regarding [the] reduction of skin microflora following a six-month treatment." (D.I. 70 at 11; *see also* Tr. at 15 (Defendants acknowledging that Example 38 is "the only example of a description of a test that was done"))

The prosecution history provides further support for Plaintiffs' construction. During prosecution, the applicant cited Example 38 as providing "[l]iteral support" for the disputed claim language, as well as *Skidmore 2003*, a publication pertaining to the same study. (D.I. 62-3 Ex. 17 at 115; *see also* D.I. 70-1 Ex. E at 115) Additionally, "in allowing the . . . '506 patent to issue," the Examiner partly "relied . . . on the findings reported in Example 38." (D.I. 70 at 11; *see also* D.I. 62-3 Ex. 23 at 208)

Defendants argue that "Example 38 is merely exemplary" and, thus, provides no "special definition for achieving 'no reduction of skin microflora during a six-month treatment.'" (D.I. 74 at 11) While these statements are literally true, the Court finds it equally true that Example 38 provides the strongest intrinsic evidence of what the applicant intended to convey by the disputed claim term.

Defendants further contend that Plaintiffs' proposed construction "does not faithfully reflect Example 38" because it "interprets . . . claim language 'during a six-month treatment' as only 'at baseline and month 6,' i.e., the start and end days of treatment." (D.I. 69 at 10) Defendants contend this is not how "during" is used in the patents. Pointing to Example 38, which notes among its "Exclusion Criteria" that subjects not have used certain drugs "during" the past six months – i.e., "at any time over the course of [the] six-month treatment" (*id.* at 11) –

Defendants argue that "during" has to mean that there is no reduction of skin microflora at any point over the six months. However, as Plaintiffs explain, Defendants' "analysis . . . focus[es] on how the word 'during' was used in an entirely unrelated context – a description of what other medications were precluded from use prior to or during the study – rather than the description of how skin microflora during a six-month treatment was actually assessed." (D.I. 75 at 5-6) (emphasis omitted) Defendants' position essentially asks the Court to read the term "during a six-month treatment" to mean "during ***any point within*** a six-month treatment," but they provide no persuasive basis for the Court to do so.

Accordingly, the Court will adopt Plaintiffs' proposed construction.

B. "subantibacterial amount" and "an amount that is effective to treat the papules and pustules of rosacea, but has substantially no antibiotic activity"[3]

Plaintiffs "an amount that does not significantly inhibit the growth of microorganisms, e.g., bacteria; that is, from a clinical point of view, does not inhibit a significant amount of microorganisms, e.g., bacteria even though a few of the more sensitive bacterial cells may be inhibited"
Defendants "an amount that does not significantly inhibit the growth of microorganisms, e.g., bacteria"
Court "an amount that does not significantly inhibit the growth of microorganisms, e.g., bacteria; that is, from a clinical point of view, does not inhibit a significant amount of microorganisms, e.g., bacteria even though a few of the more sensitive bacterial cells may be inhibited"

Plaintiffs argue that their proposed construction is "taken directly from the intrinsic

[3]This term appears in claims 1 and 28-30 of the '267 patent and in claims 1 and 20 of the '572 patent. (*See* D.I. 77 at 3-4)

evidence" – specifically, "from key statements made during [the] prosecution of the . . . '267 patent." (D.I. 70 at 14) Defendants respond that Plaintiffs' proposed construction is "not supported by the intrinsic evidence." (D.I. 74 at 7) The Court agrees with Plaintiffs.

During prosecution of the '267 patent, "the applicant emphasized the clinical perspective of a [person of skill in the art] regarding the phrases 'substantially no antibiotic activity' and "sub-antibiotic dose.'"[4] (D.I. 70 at 14) In particular, the applicant noted that "[a] skilled artisan would have no difficulty understanding the phrase[s] 'substantially no antibiotic activity'" and "sub-antibiotic dose" to mean that a "few of the more sensitive bacterial cells may be inhibited by a sub-antibiotic dose of a tetracycline[, but] a significant amount of bacteria is not inhibited." (D.I. 62-2 Ex. 11 at 102) (emphasis omitted) Thus, "from a clinical point of view," a skilled artisan "would not consider" a sub-antibiotic dose to "inhibit[]" the growth of bacteria. (*Id.*) (emphasis omitted) Plaintiffs' proposed construction "tracks" and "incorporat[es] th[is] definitional language from the prosecution history." (D.I. 75 at 8; *see also* Tr. at 29)

Defendants note that in a previous case, the Court construed "substantially no antibiotic activity" and "sub-antibiotic dose" as "an amount that does not significantly inhibit the growth of microorganisms, e.g., bacteria." *See Research Found. of State Univ. of N.Y. v. Mylan Pharm., Inc.*, C.A. No. 09-184-LPS ("*Mylan* Action") D.I. 134 at 17, D.I. 166 at 3. Defendants also observe that the Court's previous construction was "key" to the Court's finding of noninfringement of the '272 patent and the '572 patent in the *Mylan* Action. (D.I. 69 at 6 (internal quotation marks omitted); *see also Mylan* Action D.I. 278 at 39-43) Consequently,

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[4]During prosecution, the applicant used the phrases "substantially no antibiotic activity" and "sub-antibiotic dose" synonymously. (*See* D.I. 62-2 Ex. 11 at 102)

according to Defendants, Plaintiffs are collaterally estopped from asserting their proposed different construction of these terms in the instant action. (*See* D.I. 74 at 6)

The Court is not persuaded that Defendants' estoppel argument should lead the Court to adopt Defendants' proposed construction. As explained above, Plaintiffs' proposed construction "tracks the language in the applicant['s] statements made during prosecution." (D.I. 75 at 8) In other words, the construction Plaintiffs are advocating is well-supported by the intrinsic evidence and is the correct construction. Hence, even assuming that Plaintiffs are collaterally estopped from arguing for that construction, it is the construction the Court should – and would – adopt nonetheless.

C. "Delayed release" and "DR"[5]

Plaintiffs Plain and ordinary meaning Or, alternatively: "release of a drug at a time other than immediately following oral administration"
Defendants "release of a drug at a time other than immediately following oral administration through the use of an enteric coating or uncoated matrix tablet"
Court "release of a drug at a time other than immediately following oral administration"

In an *inter partes* review ("IPR"), the Patent Trial and Appeal Board ("PTAB") construed the terms "delayed release" and "DR." (*See* D.I. 62-4 Ex. 29 at 51) Plaintiffs urge the Court to

[5]This term appears in claims 1, 15, and 20 of the '532 patent; claims 1, 8, 10-11, 19, and 22 of the '740 patent; claims 1, 3, 6, 8-9, 17, and 20 of the '405 patent; claims 1, 3, 5, 7-8, 17, and 21 of the '406 patent; claims 1-2, 5, 7-8, and 16-17 of the '364 patent; and claims 1, 5, 17, 19-20, 24, 35, and 37 of the '478 patent. (*See* D.I. 77 at 4)

adopt the same construction as the PTAB, which they contend is also supported by the specification. (*See* D.I. 70 at 17) Defendants argue that their proposed construction, adding limitations to the PTAB's construction, better comports with the specification. (*See* D.I. 74 at 20) The Court again agrees with Plaintiffs.

Although the PTAB's claim construction and analysis are not controlling, here it accurately reflects the "plain and ordinary meaning of the term 'delayed release'" and "how a POSA would have understood [the term 'delayed release'] in view of the intrinsic evidence." (D.I. 75 at 12; *see also* Tr. at 57 (Defendants acknowledging that there was nothing inconsistent between PTAB's analysis and *Phillips*)) Nor is there anything in the specification to support narrowing the PTAB's construction in the manner proposed by Defendants. (*See* D.I. 70 at 17; *see also* D.I. 62-4 Ex. 35 ¶ 20 (Defendants' expert declarant in IPR proceedings acknowledging that "a POSA would have interpreted the term 'delayed release' to mean release of a drug at a time other than immediately following oral administration") (internal quotation marks omitted))

Defendants' attempt to narrow the term to "enteric coatings" and "uncoated matrix tablets" is unavailing, as there is no basis to limit the scope of the claims to these exemplary embodiments disclosed in the specification. *See Phillips*, 415 F.3d at 1323 ("[T]he line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms. . . . [A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.").

D. "Portion" and "formulation"[6]

Plaintiffs Plain and ordinary meaning
Defendants "a single type of unit in a multiple unit dosage form that is [delayed] [immediate] release"
Court Plain and ordinary meaning

The parties agree that "the claimed compositions 'consist of' an [immediate release ("IR")] portion and a [delayed release ("DR")] portion," but dispute whether the claim language "requir[es] that the IR portion and the DR portion each must be composed of only a single type of unit." (D.I. 75 at 15 (internal quotation marks omitted); *see also* Tr. at 84-85 (Plaintiffs admitting that only immediate and delayed release formulations are part of the claims))

Defendants observe that "every reference" to IR and DR "portions" in the specification includes "just one IR unit and one DR unit." (D.I. 69 at 12) (internal quotation marks omitted) Even so, Defendants' construction improperly "narrow[s] the plain and ordinary meaning of [the] claim term by reference to . . . a preferred embodiment." (D.I. 75 at 15 (emphasis and internal quotation marks omitted); *Phillips*, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.")) Furthermore, as Plaintiffs note, the specification also contains "more general statements . . . discussing compositions with IR and DR portions that

[6]This term appears in claims 1-2, 15, and 20 of the '532 patent; claims 1, 8, 10-11, 19, and 22 of the '740 patent; claims 1, 6, 8-9, 17, and 20 of the '405 patent; claims 1, 3, 5, 7-8, 17, and 21 of the '406 patent; claims 1-2, 5, 7-8, and 16-17 of the '364 patent; and claims 1, 5, 17, 19-20, 24, 35, and 37 of the '478 patent. (*See* D.I. 77 at 5)

do not recite the specific narrowing limitations" proposed by Amneal. (D.I. 75 at 16; *see also* '532 patent col. 5 ll. 25-28, 42-43)

Nor is the Court persuaded by Defendants' prosecution history disclaimer argument. (*See* D.I. 69 at 14) Defendants note that, during prosecution, the applicant "initially proposed claims that said 'comprising' an 'immediate release (IR) portion' and a 'delayed release (DR) portion,'" which were rejected as obvious over Rudnic '766. (*Id.*) (emphasis omitted) Thereafter, Plaintiffs amended the claims to overcome the rejection by changing "comprising" to "consisting of." (*Id.* at 15) In Plaintiffs' view, "[a] review of the full prosecution history in context . . . reveals that the applicant did not distinguish Rudnic '766 in a way that supports" Defendants' proposed construction. (D.I. 75 at 17) Instead, Plaintiffs argue, the applicant "distinguished [Rudnic '766] as a full-dose antibiotic formulation containing 100-200 mg doxycycline," while the claimed invention "consists of . . . a total of 40 mg doxycycline" (*id.*) (emphasis omitted), which is "useful at sub-antibacterial amounts" (D.I. 64-1 Ex. 44 at 6-7).

"For prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (internal quotation marks and alterations omitted). Here, that standard is not met; the applicant did not clearly and unmistakably disclaim embodiments with an IR portion and multiple types of DR portions. Plaintiffs' reading of the prosecution history – that the applicant distinguished Rudnic '766 by reference to dosage amounts and antibacterial activity (*see* D.I. 75 at 17-18) – is at least one reasonable interpretation of that history. There is no argument or discussion accompanying the amendment that provides additional insight. Where, as here, "the alleged disavowal is

ambiguous, or even amenable to multiple reasonable interpretations, . . . [courts] have declined to find prosecution disclaimer." *Avid Tech.*, 812 F.3d at 1045 (internal citation and quotation marks omitted).[7]

At oral argument, Defendants stated that, even if the Court were to find (as it has) that there was no disclaimer, the parties also dispute the plain and ordinary meaning of "portion" and "formulation." (Tr. at 76) According to Defendants, the plain and ordinary meaning of these terms is "only one unit," while Plaintiffs propose it is "amount." (*Id.* at 76-77) For now, the Court construes the disputed term to have its "plain and ordinary meaning." Should the parties find they have a genuine, material dispute as to the "plain and ordinary meaning" of these terms, they shall include short briefing on the dispute in their proposed final pretrial order.

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.

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[7]During the IPR, Plaintiffs distinguished prior art by noting that the "sustained release . . . formulation approach" in the alleged prior art bore "no relation to the claimed IR/DR formulations of the . . . '740 patent" (D.I. 64-1 Ex. 64 at 15) and by arguing that the alleged prior art "did not render the specific combination of an IR portion and a DR portion obvious" (D.I. 75 at 19). As with Plaintiffs' statements during prosecution, these IPR statements also do not clearly and unambiguously disclaim all embodiments other than those containing just one IR portion and one DR portion. However, as Plaintiffs agreed at the hearing, Plaintiffs' claims do not cover embodiments that contain an IR portion, one or more DR portions, ***and*** a sustained release portion. (*See* Tr. at 84-85)